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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,829

04/09/2004

James M. Minor

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05/26/2006

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EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/821,829	Applicant(s) MINOR, JAMES M.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-13 and 17-20, drawn to a rank ordering method, classified in class 209, subclass 2.
- II. Claim 14-16, drawn to a data shuttling method, classified in class 710, subclass 33.
- III. Claim 21-27, drawn to a calibration method, classified in class 435, subclass 967.
- IV. Claim 28-33, drawn to a method of distinguishing genes, classified in class 435, subclass 4.

The inventions are independent or distinct, each from the other because:

Inventions of Group II and Groups I, III and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention of Group II is to a method of data transfer between two or more computer systems. The claims of Group II are interpreted to encompass any method of transfer data from one location to another, for example such as by bicycle messenger or carrier pigeon. The inventions of Groups I, III, or IV are directed to methods of sorting, calibration, or

distinguishing, respectively. All these methods (Groups I, III, IV) have different designs, functions and result in different effects from the method of Group I. For example, the method of data transfer (Group II) cannot rank order (Group I), distinguish genes (Group IV), or perform calibration (Group III). Thus a search for methods of data transfer would not overlap a search for either methods of rank ordering, calibrating, or distinguishing and therefore provide an undue search burden.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions of Group I and Group III are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention of Group I is directed to a method of rank ordering which is distinct from the invention of Group III, directed to method validating or calibrating. The method of Group I has a different mode of operation and effect from the method of Group III. First, the method steps of Group I and Group III are different. In the case of Group I an uncontrolled mixture of cells is used to measure cell characteristics whereas in Group III a controlled ratio mixture of cells is used to measure characteristics. Second, the measurements of the method of Group I are subjected to multidimensional statistical analysis. However, the measurements from the method of Group III are only used to determine a statistical

p-value. Third, the measurements from the method of Group I are made by employing a microarray where the method of Group III does not. Finally, the method of Group I results in a standard quadratic plot. The method of Group III results in a logarithmic plot. Thus a search for the method of rank ordering would not overlap a search of the method of calibrating and therefore provide an undue search burden.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions of Group I and Group IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention of Group I is directed to a method of rank ordering which is distinct from the invention of Group IV, method of distinguishing genes. The method of Group I has a different mode of operation from the method of Group IV as evidenced by the difference in steps between the inventions of Group I and Group IV. First, The method of Group I uses a microarray whereas the method of Group IV does not employ the use of a microarray. Second, the method of Group I uses statistical analysis to analyze obtained measurement, the method of Group IV does not use statistical analysis. The method of Group IV employs the use of a "noise cloud" to analyze obtained measurements. Finally, the effect of the method of Group I results in the rank order of cell

characteristics which is different from the effect of the method of Group IV, the identification of differentially expressed genes. Thus the inventions of Group I and Group IV would require different searches of the prior art and therefore provide an undue search burden.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions of Group III and Group IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention of Group III is directed to a method of validating or calibrating which is distinct from the invention of Group IV, directed to a method of distinguishing genes. The invention of Group III has a different mode of operation from the invention of Group IV as evidenced by the differences in steps between the methods. First, the method of Group I employs statistical analysis of measurements obtained. However, the method of Group IV does not employ statistical analysis of obtained measurements but rather uses a "noise cloud" to analyze measurements. Second, the method of Group III plots measurements on a logarithmic scale where the method of Group IV plots measurements on standard quadratic scale. Finally, the measurements of Group IV are analyzed in multi-dimensional space unlike the measurements from the method of Group III. Thus the

inventions of Group III and Group IV would require different searches of the prior art and therefore provide an undue search burden.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is

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(571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

